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| To: Jeff Peter | From: Theodore J. Criares |
| Application/Control Number: 09/995,911 | Art Unit: 1617 |
| Fax No.: 1-608-283-2275 | Phone No.: (571) 272-0625 |
| Voice No.: (608) 257-3501 | Return Fax No.: (703) 872-9306 |
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Comments:

Executed IDS 1449 for 9/8/03; 11/21/03; 3/3/04 and 4/10/04.

Number of pages __ **including this page**

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PTO/SB/08A

Substitute for PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known

Application Number 09/995,911
 Filing Date November 28, 2001
 First Name Inventor Richard B. Mazess
 Group Art Unit 1617
 Examiner Name Criares, Theodore
 Attorney Docket Number 017620-9335

Sheet 1 of 1

U.S. PATENT DOCUMENTS

| Examiner Initials | U.S. Patent Document Number | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document |
|-------------------|-----------------------------|---|---------------------------------------|
| RE | 6,143,910 | BISHOP et al. | 11/7/2000 |
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| Examiner Initials | Country Code | Foreign Patent Document Number | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document | Translation | English Abstract |
|-------------------|--------------|--------------------------------|---|---------------------------------------|-------------|------------------|
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Date Considered

12/17/04

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|---|--|--------------------------|---------------------|
| Substitute of form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Page 1 of 2 | | Complete if Known | |
| | | Application Number | 09/995,911 |
| | | Filing Date | November 28, 2001 |
| | | First Name Inventor | Mazess et al. |
| | | Group Art Unit | 1617 |
| | | Examiner Name | Theodore J. Criares |
| | | Attorney Docket Number | 017620-9335 |

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| Examiner Initials | U.S. Patent Document Number | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document |
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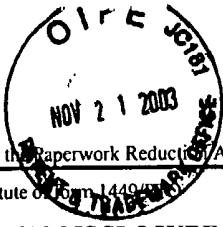
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| BA | 4,160,803 | Potts | 07/10/79 |
| BB | 4,717,721 | DeLuca et al. | 01/25/88 |
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| BR | 5,661,025 | Szoka, Jr. et al. | 08/26/97 |
| BS | 5,691,328 | Peterson et al. | 11/25/97 |

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|--------------------|--|-----------------|----------|
| Examiner Signature | | Date Considered | 12/14/04 |
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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | Complete if Known | |
| | | Application Number | 09/995,911 |
| | | Filing Date | November 28, 2001 |
| | | First Name Inventor | Mazess et al. |
| | | Group Art Unit | 1617 |
| Examiner Name | Theodore J. Criares | | |
| Sheet 2 of 1 | Attorney Docket Number | 017620-9335 | |

U.S. PATENT DOCUMENTS

| Examiner Initials | U.S. Patent Document Number | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document |
|-------------------|-----------------------------|---|---------------------------------------|
|-------------------|-----------------------------|---|---------------------------------------|

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|----|-----------|----------------|----------|
| BT | 5,739,271 | Sridhar et al. | 04/14/98 |
| BU | 5,795,882 | Bishop et al. | 08/18/98 |
| BV | 5,798,345 | Knutson et al. | 08/25/98 |
| BW | 6,503,893 | Bishop et al. | 01/07/03 |
| BX | 6,521,608 | Henner et al. | 02/18/03 |
| BY | 6,537,982 | Bishop et al. | 03/25/03 |
| BZ | 6,538,037 | Bishop et al. | 03/25/03 |

FOREIGN PATENT DOCUMENTS

| Examiner Initials | Country Code | Foreign Patent Document Number | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document | Translation | English Abstract |
|-------------------|--------------|--------------------------------|---|---------------------------------------|-------------|------------------|
| CA | Japan | 5320127 | Nisshin Flour Milling Co. | 09/29/93 | | |
| CB | Japan | 6025039 | Kurary Co. Ltd. | 02/01/94 | | |
| CC | Japan | 62000033 | General Hospital | 10/15/86 | | |
| CD | PCT | WO 93/07883 | ISIS Pharmaceuticals | 04/29/93 | | |

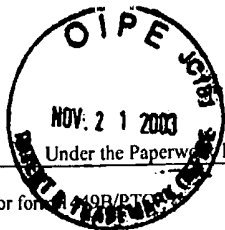
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| Substitute for form PTO/SB/08B | | | Complete if Known | | |
| | | | Application Number | 09/995,911 | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | | Filing Date | November 28, 2001 | |
| | | | First Named Inventor | Mazess et al. | |
| | | | Group Art Unit | 1617 | |
| | | | Examiner Name | Theodore J. Criares | |
| Sheet | 1 | of | 2 | Attorney Docket Number | 017620-9335 |

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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

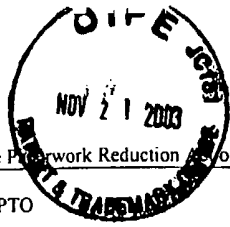
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| Examiner Initials | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published. |
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| PK | CE | Beer, T. et al., "Weekly High-Dose Calcitriol and Docetaxel in Metastatic Androgen-Independent Prostate Cancer," <i>Journal of Clinical Oncology</i> , (Jan. 2003) 21:1:123-128. |
| | CF | Blazsek, I. et al. "Combined Differentiation Therapy in Myelodysplastic Syndrome with Retinoid Acid, 1 α ,25 Dihydroxyvitamin D ₃ , and Prednisone," 16:4:259-264 (Abstract). |
| | CG | Carter, Stephen K. et al. <i>Chemotherapy of Cancer</i> 2 nd Ed. (1981) 362-365. |
| | CH | Cho, Y.L. et al., "Combined Effects of 1,25-Dihydroxyvitamin D ₃ and Platinum Drugs on the Growth of MCF-7 Cells," <i>Cancer Research</i> , (June 1991) 51:2848-2853. |
| | CI | Defacque, H. et al., "Different Combinations of Retinoids and Vitamin D ₃ Analogs Efficiently Promote Growth Inhibition and Differentiation of Myelomonocytic Leukemia Cell Lines," <i>J. Pharmacology and Experimental Therapeutics</i> , (1994) 271:193-199. |
| | CJ | Endo, K. et al., "Effect of Combination Treatment with Vitamin D Analog (OCT) and a Bisphosphonate (AHPBP) in a Nude Mouse Model of Cancer-Associated Hypercalcemia," <i>Journal of Bone and Mineral Research</i> , (1998) 13:9:1378-1383. |
| | CK | Hershberger, P. et al. "Calcitriol (1,25-Dihydroxycholecalciferol) Enhances Paclitaxel Antitumor Activity <i>in Vitro</i> and <i>in Vivo</i> and Accelerates Paclitaxel-induced Apoptosis," <i>Clinical Cancer Research</i> , (April 2001) 7:1043-1051. |
| | CL | Johnson, C. et al., "Vitamin D-related Therapies in Prostate Cancer," <i>Cancer and Metastasis Review</i> 21, (2002) pp. 147-158. |
| | CM | <i>Journal of Bone and Mineral Research</i> , (1994) 9:5:607-614. |
| | CN | Kim, S. et al., "Potentiation of 1,25-Dihydroxyvitamin D ₃ -Induced Differentiation of Human Promyelocytic Leukemia Cells into Monocytes by Costunolide, a Germacranolide Sesquiterpene Lactone," <i>Biochem. Pharmacology</i> , (2002) 64:1233-1242. |
| | CO | Londowski, J.M. et al., "Biological Activity of the C-1, C-3, C-25, β -D-Glucopyranosides of 1,25-Dihydroxyvitamin D ₃ ," <i>J. Pharmacology Expr. Ther.</i> , (1986) 237:3:837-840. |
| | CP | Mathias, C.J. et al., "Tumor-Selective Radiopharmaceutical Targeting Via Receptor-Mediated Endocytosis of Gallium-67-Deferoxamine-Folate," <i>J. Nucl. Med.</i> (1996), 37(6):1003-1008. |
| | CQ | Moffatt, K. et al., "1 α ,25-Dihydroxyvitamin D ₃ and Platinum Drugs Act Synergistically to Inhibit the Growth of Prostate Cancer Cell Lines," <i>Clinical Cancer Research</i> , (March 1999) 5:695-703. |
| | CR | Muindi, J. et al., "Pharmacokinetics of High-Dose Oral Calcitriol: Results From a Phase 1 Trial of Calcitriol and Paclitaxel," <i>Clinical Pharmacology & Therapeutics</i> , (Dec. 2002) pp. 648-659. |

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| Examiner Signature | | Date Considered | 12/14/04 |
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| Substitute for form 1449B/PTO | | | Complete if Known | | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | | Application Number | 09/995,911 | |
| | | | Filing Date | November 28, 2001 | |
| | | | First Named Inventor | Mazess et al. | |
| | | | Group Art Unit | 1617 | |
| | | | Examiner Name | Theodore J. Criares | |
| Sheet | 2 | of | 2 | Attorney Docket Number | 017620-9335 |

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| OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS | |
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| Examiner Initials | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published. |

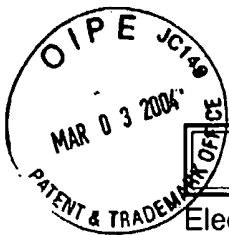
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| CS | Packman, K. et al. "Combination Treatment of MCF-7 Xenografts with the Vitamin D ₃ Analog EB1089 and Antiestrogens," (Vitamin D Endocrine Workshop, Nashville, TN May 27-June 1, 2000) pp. 511-514. |
| CT | Ravid, A. et al., "1,25-Dihydroxyvitamin D ₃ Enhances the Susceptibility of Breast Cancer Cells to Doxorubicin-induced Oxidative Damage," <i>Cancer Research</i> , (February 15, 1999) 59:862-867. |
| CU | Siwinska, A. et al. "Potentiation of the Antiproliferative Effect <i>in Vitro</i> of Doxorubicin, Cisplatin and Genistein by New Analogues of Vitamin D," <i>Anticancer Research</i> , (2001) 21:1925-1929. |
| CV | Slapak, C. et al., "Treatment of Acute Myeloid Leukemia in the Elderly with Low-Dose Cytarabine, Hydroxyurea, and Calcitriol," <i>Amer. J. Hematology</i> , (1992) 41:178-183. |
| CW | Song, X.D. et al., "Bryostatin-1 and 1 α ,25-Dihydroxyvitamin D ₃ Synergistically Stimulate the Differentiation of NB4 Acute Promyelocytic Leukemia Cells," <i>Leukemia</i> , (1999) 13:275-281. |
| CX | Studzinski, G. et al., "Potentiation by 1- α ,25-Dihydroxyvitamin D ₃ of Cytotoxicity to HL-60 Cells Produced by Cytarabine and Hydroxyurea," <i>J. National Cancer Inst.</i> , (April 1986) 76:4:641-648. |
| CY | Suzuki, Y. et al., "The Enhancement of the Chemotherapeutic Effects on Human Prostate Cancer Cell - The Combination with the Growth Factor Interaction Inhibitor (Suramin)," <i>Acta Urologica</i> (1993) 12:1215-1220, (Abstract). |
| CZ | Swami, S. et al. "1 α ,25-Dihydroxyvitamin D ₃ Down-Regulates Estrogen Receptor Abundance and Suppresses Estrogen Actions in MCF-7 Human Breast Cancer Cells," <i>Clinical Cancer Research</i> , (Aug. 2000) 6:3371-3379. |
| DA | Torres, R. et al., "Etoposide Stimulates 1,25-Dihydroxyvitamin D ₃ Differentiation Activity, Hormone Binding and Hormone Receptor Expression in HL-60 Human Promyelocytic Cells," <i>Molecular and Cellular Biochemistry</i> , (2000) 208:157-162. |
| DB | Wang, Q. et al., "1,25-Dihydroxyvitamin D ₃ and All-trans-Retinoic Acid Sensitize Breast Cancer Cells to Chemotherapy-induced Cell Death," <i>Cancer Research</i> , (April 2000) 60:2040-2048. |
| DC | Wang, X. et al., "Inhibition of p38 MAP Kinase Activity Up-Regulates Multiple MAP Kinase Pathways and Potentiates 1,25-Dihydroxyvitamin D ₃ -Induced Differentiation of Human Leukemia HL60 Cells," <i>Experimental Cell Research</i> , (2000) 258:425-437. |
| DD | Yu, W. et al., "Enhancement of 1,25-Dihydroxyvitamin D ₃ -Mediated Antitumor Activity with Dexamethasone," <i>J. National Cancer Inst.</i> , (January 1998) 90:2:134-141. |

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| Examiner Signature | | Date Considered | 12/14/04 |
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Stylesheet Version v18.0

| Title of Invention | TREATMENT OF HYPERPROLIFERATIVE DISEASES USING ACTIVE VITAMIN D ANALOGUES | | | | | | |
|---|---|--|------------|------------------|------|---|----------|
| Application Number: | | 09/995911 | | | |  | |
| Confirmation Number: | | 4126 | | | | | |
| First Named Applicant: | | Richard Mazess | | | | | |
| Attorney Docket Number: | | 0176209335 | | | | | |
| Art Unit: | | 1617 | | | | | |
| Examiner: | | Theodore Criares | | | | | |
| Search string: | | (6582710 or 6599513 or 6642218 or 20010002396 or 20010025036 or 20010049365 or 20010051617 or 20020006917 or 20020049344 or 20020068723 or 20020091109 or 20020099039 or 20020103173 or 20020132799 or 20030040508 or 20030109506 or 20030119795 or 20030149005 or 20030149006 or 20030166622 or 20030171342 or 20030195171 or 20030195176 or 20030195259 or 20030216359 or 20040019023).pn. | | | | | |
| <h3>US Patent Documents</h3> | | | | | | | |
| Note: Applicant is not required to submit a paper copy of cited US Patent Documents | | | | | | | |
| init | Cite.No. | Patent No. | Date | Patentee | Kind | Class | Subclass |
| <input checked="" type="checkbox"/> | 1 | 6582710 | 2003-06-24 | Deckers et al | | | |
| <input checked="" type="checkbox"/> | 2 | 6599513 | 2003-07-29 | Deckers et al | | | |
| <input checked="" type="checkbox"/> | 3 | 6642218 | 2003-11-04 | Steinmeyer et al | | | |
| <h3>US Published Applications</h3> | | | | | | | |
| Note: Applicant is not required to submit a paper copy of cited US Published Applications | | | | | | | |
| init | Cite.No. | Pub. No. | Date | Applicant | Kind | Class | Subclass |
| <input checked="" type="checkbox"/> | 1 | 20010002396 | 2001-05-31 | Achkar | | | |
| <input checked="" type="checkbox"/> | 2 | 20010025036 | 2001-09-27 | DeLuca et al | | | |



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|---|----|-------------|------------|------------------|
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| | 8 | 20020091109 | 2002-07-11 | Takenouchi et al |
| | 9 | 20020099039 | 2002-07-25 | Takenouchi et al |
| | 10 | 20020103173 | 2002-08-01 | Takenouchi et al |
| | 11 | 20020132799 | 2002-09-19 | Takenouchi et al |
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| | 13 | 20030109506 | 2003-06-12 | Hayes et al |
| | 14 | 20030119795 | 2003-06-26 | Henner et al |
| | 15 | 20030149005 | 2003-07-07 | Posner et al |
| | 16 | 20030149006 | 2003-07-07 | Steinmeyer et al |
| | 17 | 20030166622 | 2003-09-04 | Steinmeyer et al |
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| | 19 | 20030195171 | 2003-10-16 | Daifotis et al |
| | 20 | 20030195176 | 2003-10-16 | Kawase et al |
| | 21 | 20030195259 | 2003-10-16 | Bernardon et al |
| | 22 | 20030216359 | 2003-11-20 | Johnson et al |
| ✓ | 23 | 20040019023 | 2004-01-29 | Morikawa et al |

Remarks

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ELECTRONIC INFORMATION DISCLOSURE STATEMENT

Electronic Version v18

Stylesheet Version v18.0

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| Title of Invention | TREATMENT OF HYPERPROLIFERATIVE DISEASES USING ACTIVE VITAMIN D ANALOGUES | | | | | | |
| Application Number: 09/995911 | | | | | | | |
| Confirmation Number: 4126 | | | | | | | |
| First Named Applicant: Richard Mazess | | | | | | | |
| Attorney Docket Number: 0176209335 | | | | | | | |
| Examiner: Theodore Criares | | | | | | | |
| Search string: (4948789 or 5260290 or 5366965).pn. | | | | | | | |
| US Patent Documents | | | | | | | |
| Note: Applicant is not required to submit a paper copy of cited US Patent Documents | | | | | | | |
| init | Cite.No. | Patent No. | Date | Patentee | Kind | Class | Subclass |
| <input checked="" type="checkbox"/> | 1 | 4948789 | 1990-08-14 | Slatopolsky | | | |
| <input checked="" type="checkbox"/> | 2 | 5260290 | 1993-11-09 | DeLuca et al | | | |
| <input checked="" type="checkbox"/> | 3 | 5366965 | 1994-11-22 | Strein | | | |
| Remarks | | | | | | | |
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| Examiner Name | | | | Date | | | |
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